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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,451	09/12/2003	Kyle Gee	IVGN 706	5248
23358 7590 11/08/2007 INVITROGEN CORPORATION C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			EXAMINER VENCI, DAVID J	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 11/08/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/661,451

Applicant(s)

GEE ET AL.

Examiner

David J. Venci

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 15, 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 36-42 and 48-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 36-42 and 48-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Notice to Comply; STIC RAW SEQUENCE LISTING
ERROR REPORT

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DETAILED ACTION

Examiner acknowledges Applicants' reply filed February 15, 2007. Applicants cancel claims 8-35 and 43-47, and add new claims 53-56. Currently, claims 1-7, 36-42 and 48-56 are under examination.

Sequence Compliance

APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Examiner acknowledges receipt of a Sequence Listing and a Computer Readable Form of the Sequence Listing, filed February 15, 2007. However, Applicants' submitted Computer Readable Form of the Sequence Listing fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio
(<http://www.uspto.gov/ebs/efs/downloads/documents.htm>), EFS Submission User Manual - ePAVE)
2. Mailed to:

**U.S. Patent and Trademark Office
Box Sequence, P.O. Box 2327
Arlington, VA 22202**

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 6, 39, 40, 49 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 40 and 50, the phrase "B is a binding domain" is indefinite. Whether "B is a binding domain" references "a binding domain" recited in antecedent claims 39 and 49, respectively, is not clear.

In claim 55:

In the first and fourth compounds, the structure referenced by " $(_2\text{-OCCH}_2)_2\text{N}$ " is not clear.

In the first and fourth compounds, the structure referenced by " $\text{N}(\text{CH}_2\text{CO}_2)_2$ " is not clear.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36-39, 42 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Majima *et al.*, 1243 BIOCHIM. BIOPHYS. ACTA 336 (1995).

Majima *et al.* describe a staining solution comprising:

(a) a fluorescent compound (see Fig. 1, "EMA"); and

(b) a buffer comprising a metal ion (see p. 337, left column, 2.2 *Analysis of adducts of NEM with SH-compounds*, "100 mM. sodium phosphate buffer") (emphasis added).

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Claims 1-7, 36-42 and 48-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Lomas (US 2003/0077616).

Lomas describes a staining solution comprising:

(a) a fluorescent compound (see Table. 1, Affinity label, "fluorescein") capable of binding to:

1. poly-histidine (see para. [0174], "Imidazoly and Phenol Ring Biomolecule Reactive Groups"),
2. poly-arginine (see para. [0178], "Amine Biomolecule Reactive Groups") or
3. Glu-Glu (see para. [0176], "Carboxylate Biomolecule Reactive Groups");

(b) a buffer (see paragraph [0126]).

With respect to claim 48, Lomas describes a fusion protein (see e.g., paragraph [0180]-[0181]).

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Claims 1-7, 36-41, 53 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuhn & Haugland (US 5,453,517).

Kuhn & Haugland describe a staining solution comprising:

(b) a fluorescent compound (see Abstract, first sentence, "fluorescent and/or reactive derivatives of 1,2-bis-(2-aminophenoxyethane)-N,N',N'-tetraacetic acid") capable of binding to:

1. poly-histidine (see Table 1, REACT WITH, "amines"),
2. poly-arginine (see Table 1, REACT WITH, "amines") or
3. Glu-Glu (see Table 1, REACT WITH, "carboxylic acids");

(b) a buffer (see col. 1, line 28).

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Response to Arguments

In prior Office Action, claims 1-5, 36-39 and 42 were rejected under 35 U.S.C. 102(b) as being anticipated by Majima *et al.*, 1243 BIOCHIM. BIOPHYS. ACTA 336 (1995).

In response, Applicants amend independent claim 1 to require a fluorescent compound capable of binding to "poly-histidine, poly-arginine or Glu-Glu". Applicants argue that Majima *et al.* fail to describe such a fluorescent compound.

With respect to claims 1-5, Applicants' argument is persuasive.

With respect to claims 36-39, Applicants' argument is not persuasive because preamble language or language describing kit instructions (e.g., the paper kind) describing Applicants' intended use of the claimed invention do not patentably distinguish Applicants' claimed invention from Majima *et al.* because the language does not result in a structural difference between the claimed invention and the teachings of Majima *et al.*

In prior Office Action, claims 1-4, 6-7, 36-42 and 48-52 were rejected under 35 U.S.C. 102(e) as being anticipated by Lomas (US 2003/0077616).

In response, Applicants amend independent claim 1 to require a fluorescent compound capable of binding to "poly-histidine, poly-arginine or Glu-Glu". Applicants argue that Lomas fails to describe such a fluorescent compound. Furthermore, Applicants argue that Lomas describes antibodies, which are excluded from Applicants' claimed compositions.

Applicants' arguments are not persuasive.

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Lomas describes fluorescent compounds capable of binding to poly-histidine (see para. [0174], "Imidazolyl and Phenol Ring Biomolecule Reactive Groups"), poly-arginine (see para. [0178], "Amine Biomolecule Reactive Groups") or Glu-Glu (see para. [0176], "Carboxylate Biomolecule Reactive Groups"). In addition, Lomas' incidental description of antibodies does not preclude anticipation of Applicants' claimed features.

In prior Office Action, claims 1-4, 6-7, 36-41 and 48-51 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 20-22 and 24 (misnumbered) of copending Application No. 10/966,536.

On March 29, 2007, the Office imposed a Restriction Requirement in copending Application No. 10/966,536.

Accordingly, this rejection is withdrawn.

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Conclusion

Claims 54 and 56 are free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Assistant Examiner
Art Unit 1641

djv


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No. 10/661,451	Applicant(s) Haugland, et al.	
	Examiner D. Venci	Art Unit 1641	

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510

For CRF Submission Help, call (571) 272-2501/2583.

PatentIn Software Program Support

Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number:

10/661,451

Source:

STW/6

Date Processed by STIC:

2/20/07

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.4.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/ebc/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):
U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/10/06

Raw Sequence Listing Error Summary

ERROR DETECTED

SUGGESTED CORRECTION

SERIAL NUMBER:

10/661,451

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1 **Wrapped Nucleics**
Wrapped Aminos The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
- 2 **Invalid Line Length** The rules require that a line not exceed 72 characters in length. This includes white spaces.
- 3 **Misaligned Amino**
Numbering The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
- 4 **Non-ASCII** The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
- 5 **Variable Length** Sequence(s) contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
- 6 **PatentIn 2.0**
"bug" A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) . Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
- 7 **Skipped Sequences**
(OLD RULES) Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
(i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading)
(xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
This sequence is intentionally skipped

Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.
- 8 **Skipped Sequences**
(NEW RULES) Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence.
<210> sequence id number
<400> sequence id number
000
- 9 **Use of n's or Xaa's**
(NEW RULES) Use of n's and/or Xaa's have been detected in the Sequence Listing.
Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
- 10 **Invalid <213>**
Response Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence
- 11 **Use of <220>** Sequence(s) missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
- 12 **PatentIn 2.0**
"bug" Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
- 13 **Misuse of n/Xaa** "n" can only represent a single nucleotide; "Xaa" can only represent a single amino acid



IFW16

RAW SEQUENCE LISTING

DATE: 02/20/2007

PATENT APPLICATION: US/10/661,451

TIME: 11:22:19

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3 <110> APPLICANT: Invitrogen Corporation
 4 Gee, Kyle
 5 Hart, Courtenay
 6 Leung, Wai-Yee
 7 Patton, Wayne
 8 Rukavishnikov, Aleksey
 9 Haugland, Richard
 10 Diwu, Zhenjun
 12 <120> TITLE OF INVENTION: Site-Specific Labeling Of Affinity Peptides In Fusion

Proteins

14 <130> FILE REFERENCE: IVGN 706
 16 <140> CURRENT APPLICATION NUMBER: 10/661,451
 17 <141> CURRENT FILING DATE: 2003-09-12
 19 <150> PRIOR APPLICATION NUMBER: 60/458,472
 20 <151> PRIOR FILING DATE: 2003-03-28
 22 <150> PRIOR APPLICATION NUMBER: 60/410,612
 23 <151> PRIOR FILING DATE: 2002-09-12
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 58 Thr Asp Phe Leu Tyr Lys
 59 1 5

62 <210> SEQ ID NO: 4
 63 <211> LENGTH: 9
 64 <212> TYPE: PRT
 65 <213> ORGANISM: Amino Acid

Pass Not Comp
 Corrected Sequence Needed
 (ps1-2) @

← See item
 #10 on error
 Summary
 sheet,

Fix:
 Per Sequence Rules,
 <213> responses has
 to be either Artificial
Unknown or Genus/
Species. 2/20/2007

RAW SEQUENCE LISTING
PATENT APPLICATION: US/10/661,451

DATE: 02/20/2007
TIME: 11:22:19

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125 1 5

Same

errors

See item

#10 on

error

Summary
Sheet.

VERIFICATION SUMMARY

DATE: 02/20/2007

PATENT APPLICATION: US/10/661,451

TIME: 11:22:20

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